REMARKS

Claims 37 and 46-50 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking disclosure with respect to the recited dosage range. Although Applicants do not necessarily concur, they seek to advance prosecution by deleting the claim language for which support has been alleged to be lacking. Accordingly, the rejection under § 112, first paragraph, is believed to be moot.

Claims 37 and 46-48 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by the data disclosed in relation to "Patient Profile 2" in Figure 1 and in Figure 2 of Hubbard, *et al., Journal of Pharmaceutical Sciences* **1989**, *78:11*, 944 ("the Hubbard reference"). Applicants respectfully request reconsideration because the cited disclosure in the Hubbard reference is not anticipatory. The reference, for example, does not disclose or suggest any method that achieves "a substantially ascending methylphenidate plasma drug concentration over a time period of about 5.5 hours" following administration of a pharmaceutically acceptable composition comprising methylphenidate and a pharmaceutically acceptable carrier. As is discussed in the accompanying declaration of inventor Suneel Gupta, the graphs provided in Figures 1 and 2 plot methylphenidate plasma concentrations in log scale, such that the distance between the various data points is compressed along the y-axis (Gupta Declaration, ¶4). In each of these graphs, for example, the distance along the y-axis between 1.0 g/ml and 10.0 g/ml, respectively, is the ***same*** as that between 10.0 g/ml and 100.0 g/ml, respectively, even though the difference between 1.0 g/ml and 10.0 g/ml (i.e., 9.0 g/ml) is ***ten time less*** than the difference between 10.0 g/ml and 100.0 g/ml (i.e., 90.0 g/ml) (*id.*). When re-plotted on a non-logarithmic basis (as shown in Dr. Gupta's declaration), the data that the Hubbard reference provides in Figure 1 for "Patient Profile 2" and in Figure 2 clearly do not disclose or suggest Applicants' claimed "substantially ascending methylphenidate plasma drug concentration over a time period of about 5.5 hours following ... administration" (*id.* at ¶¶4,5). In fact, the data in both instances discloses substantial *decrease* in methylphenidate plasma concentration over the relevant interval. Accordingly, Applicants respectfully request that the rejection for alleged anticipation be withdrawn.

Claims 37 and 46-50 stand rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over certain claims of Application Serial No. 09/253,317 because both sets of claims allegedly involve "administering methylphenidate at the ascending rate" (Office Action at page 4). Applicants note, however, that the instant claims are not limited to methods that involve administration of methylphenidate at an ascending rate. Moreover, the Office Action does not demonstrate that those of ordinary skill in the art having the claims of Application Serial No. 09/253,317 before them would have found the subject matter of the instant claims to have been obvious. Those of ordinary skill, for example, would have recognized that a variety of factors (such as the extent to which a drug of interest is cleared from a patient's body) affects plasma drug concentration, such that the use of an ascending drug release rate might not result in an ascending drug plasma concentration. Accordingly, the rejection for alleged obviousness-type double patenting lacks adequate basis and should be withdrawn.

Claims 51-62 have been added. Support for these claims may be found throughout the specification, for example, in examples 1-3 and 6-9 where particular drug concentrations are exemplified.

Applicants invite the Examiner to contact their undersigned representative if any questions arise or further information regarding the instant patent application is needed.

In view of the foregoing, however, Applicants submit that the pending claims are in condition for ready allowance, and therefore respectfully request an early indication of allowability.

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